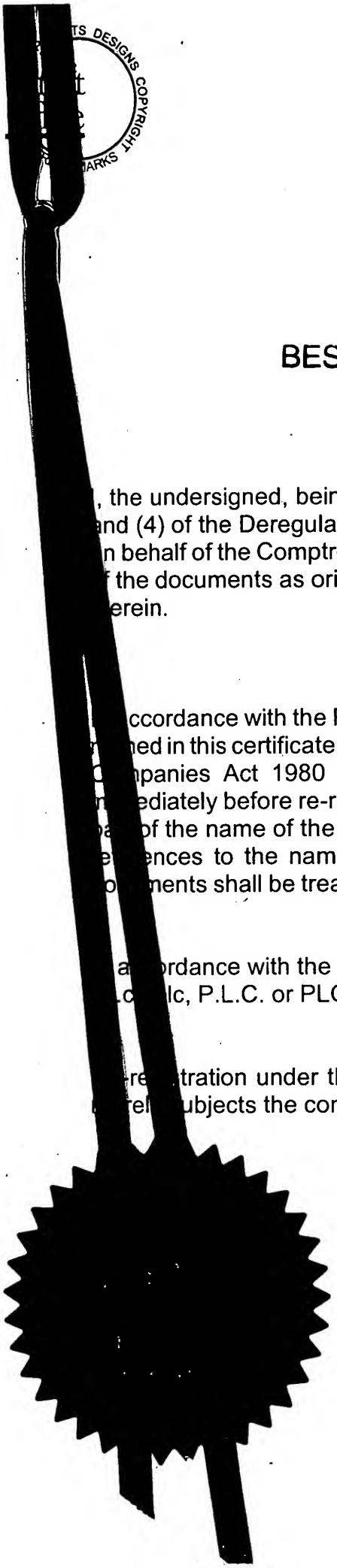


CERTIFIED COPY OF PRIORITY DOCUMENT

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

BEST AVAILABLE COPY

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by PLC, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed J Evens.

Dated 2 November 2005

Patents Form 1/77

Patents Act 1977
(Rule 16)

1/77

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
South Wales
NP10 8QQ

1. Your reference

R02/01

2. Patent application number
(The Patent Office will fill in this part)

0214881.5

27 JUN 2002

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

UNIPATH LTD
~~c/o~~ PRIORY PARK
BEDFORD MK44 3U

Patents ADP number *(if you know it)* 6820989002

If the applicant is a corporate body, give the country/state of its incorporation

UNITED KINGDOM

4. Title of the invention

ASSAY DEVICE AND APPARATUS

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

UNIPATH LTD
c/o M.P. ANDREWS
PRIORY PARK
BEDFORD MK44 3UP

Patents ADP number *(if you know it)* 841190 0001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

YES

Patents Form 1/77

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

Description 3 ✓

Claim (s) 1 ✓

Abstract

Drawing (s) 4 ✓

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*

Request for preliminary examination and search *(Patents Form 9/77)*

Request for substantive examination *(Patents Form 10/77)*

Any other documents *(please specify)*

11. I/We request the grant of a patent on the basis of this application.

Signature M.P. Andrews Date 27 June 20

12. Name and daytime telephone number of person to contact in the United Kingdom M. P. ANDREWS 01234 835479

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

a) *If you need help to fill in this form or you have any questions, please contact the Patent Office on 08459 500505.*

b) *Write your answers in capital letters using black ink or you may type them.*

c) *If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.*

d) *If you have answered 'Yes' Patents Form 7/77 will need to be filed.*

e) *Once you have filled in the form you must remember to sign and date it.*

f) *For details of the fee and ways to pay please contact the Patent Office.*

R02/01

Description

In the field of diagnostics, it is widely accepted that harnessing the properties of various types of luminescence, such as fluorescence, has allowed for improved assay sensitivity and accurate quantification of analyte levels compared to more traditional methods employing colour detection. In the case of fluorescence, having lamps to provide the excitation light, and some sort of detection system - such as a camera or photodiode - to quantify the emission light has allowed for the detection of very low levels of the fluorescent molecules. Through attaching these fluorescent molecules to other molecules capable of taking part in binding events i.e. creating a label, low levels of analyte can be detected and quantified.

One drawback with the use of fluorescent has been the perceived need for instrumentation to detect the light they generate. Both an excitation source and a photodetector have generally been provided resulting in large and/or expensive instruments. Furthermore the luminescent signals detected require processing before interpretation by a user. To date, this has resulted in specific reading instruments, which are generally quite sizeable. This is because they also have to incorporate various other components, such as those involved in light detection, and also have sufficient processing power to produce the quantified result.

To date, visually read rapid qualitative assays incorporating coloured labels such as gold sol and blue latex particles have given useful but limited sensitivity. This is primarily due to the well known inherent insensitivity of light absorption, which is how colour is detected. Whilst this has allowed for acceptable assessment of analytes such as hCG (human chorionic gonadotrophin) in the urine of pregnant women, there is clearly a need for more sensitive rapid qualitative assays for many other analytes. These could include, but are not limited to, some of the known cardiac risk markers, hormones involved in reproductive cycles, and antigens associated with infectious diseases.

Luminescence is generally understood to be inherently more sensitive than light absorption. This is often expressed in terms that it is experimentally easier to detect a small amount of light signal against the intrinsically very low background level, whereas for sensitive light absorption, whether it is light transmission or reflectance, what is detected is the small difference between two larger signals.

We have discovered that with the right combination of factors it is possible to exploit this inherent sensitivity of luminescence, especially fluorescence, in order to provide an device for the qualitatative detection of an analyte or analytes having a significantly greater sensitivity than seen in conventional visually read colour based assays.

One embodiment provides for an apparatus for use with an assay device for the detection of an analyte, whereby said apparatus comprises a housing having a means for holding or accommodating an assay device, an excitation source provided within the housing and capable of exciting the luminescent labelled particles which are present in or on the assay device, as well as a window positioned on an exterior surface of said housing through which the user may view the light emitted as a consequence of the excitation of the luminescent particles. The housing would be typically made of a plastic that would be impervious to external light.

The means for holding the assay device could be a slot provided on the exterior of the housing through which the assay carrier could at least be partially placed. The means would also be capable of ensuring that the assay device would be correctly located at a precise position within the housing.

The assay device would typically be disposed between the excitation source and the window, such that light would shine onto the assay carrier and emitted light viewed through a window situated on an opposite side of said device. Alternatively the window might be on the same side as the excitation source, in which case the emitted light could be reflected from a mirror.

The assay device itself may be of the heterogeneous lateral flow type such as described in EP0291194 whereby a porous carrier is provided with a mobilisable luminescent labelled species, which is capable of specifically binding with the analyte of interest. Typically the species will be an antibody but could alternatively be capture agents selected from species such as antigens, nucleic acids, lectins, or enzymes . Downstream of the mobilisable first species and also provided on the porous carrier, is a second species immobilised within a capture zone capable of binding with the first species.

Alternatively, the assay device may be of the homogeneous type. The requirement is that new luminescent signal appears in the homogeneous assay fluid as a result of the assay reactions.

As a further alternative, the carrier may have a planar surface as opposed to a porous one.

The assay device will be positioned within the housing such that excitation source will be capable of exciting the luminescently labelled species. The window would also be positioned such that the user could view the resultant emitted light. The reading window is designed such that the luminescent emission may be viewed in the presence of ambient lighting. A filter may also be disposed between the excitation source and user, for example provided on the surface of the window to filter out light that might be of a harmful frequency to the user, such as UV light. To be useful in clinical or domestic situations such a reader should ideally be very cheap to produce, possibly disposable. Thus the invention also provides for a one-piece integrated disposable apparatus and assay device.

A preferred embodiment of the invention comprises a typical lateral flow assay together with a purpose designed reading unit.

The lateral flow immunoassay is provided, as described in Patent EP291194 - Immunoassays and devices therefor – having a porous carrier containing mobilisable polystyrene microspheres, inside which a fluorescent dye of choice is immobilised, coated with an antibody against the analyte of choice.

The housing of the apparatus comprises an ultra-violet LED, such as the Roithner Lasertechnik RLT370-110 UV emitter, and a lithium cell power source which has a specifically designed recessed viewing window covered with ultra-violet protective material (see drawings).

Thus a sample suspected of containing the analyte of interest is applied to the porous carrier. The presence of sufficient analyte in a sample will cause the formation of a 'sandwich' interaction at the capture zone in the lateral flow assay, whereby the polystyrene microspheres become immobilised. The assay device may be placed within the apparatus either prior to or after the sample is added. The excitation source could either be activated manually eg by pressing a switch or button or it could be activated automatically by insertion of the assay device into the apparatus. When sufficient particles are bound, the emitted light will then be visible to the naked eye. In a model assay system, levels of hCG as low as 0.5 mIU/ml have been visually detected in this manner. A similar assay involving blue coloured latex particles allowed for reliable detection of between 5 and 10 mIU/ml. Therefore the embodiment has allowed for a 10 to 20-fold increase in overall assay sensitivity. This

reading device can be used in typical ambient light conditions such as in a room lit by fluorescent strip lights. It is also significantly cheaper to produce than many of the instruments on the market.

What is claimed is:

R02/01

WHAT IS CLAIMED IS:

1. An apparatus for use with an assay device for the determination of the presence of an analyte comprising a housing having

   means for accommodating the assay device at least partially within said housing

   an excitation means provided within said housing capable of exciting luminescent labels of interest present on or within the assay device

   a viewing window provided on an exterior surface of said housing specifically designed for viewing the resultant luminescent light obtained as a consequence of said excitation.

2. An apparatus as set forth in claim 1 whereby ultra violet light is used as the excitation means.

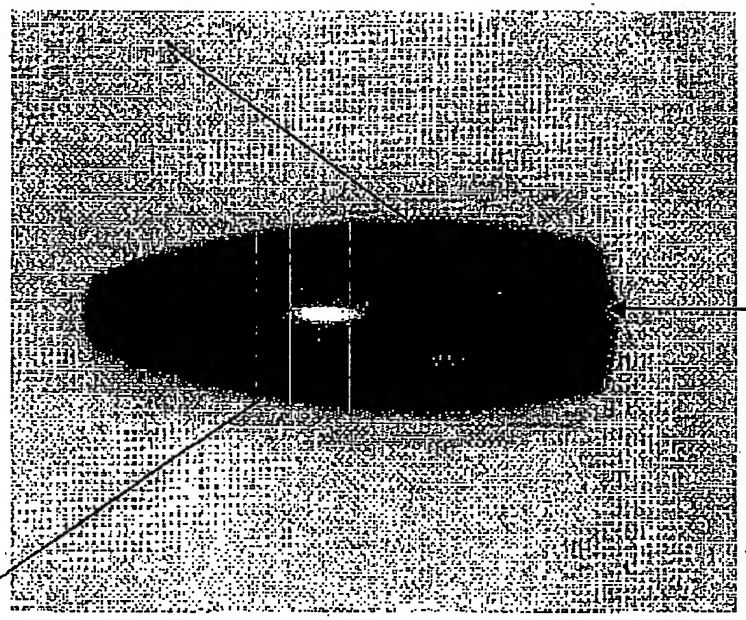
3. An apparatus as set forth in claim 1 whereby filters are disposed within or on said housing are used to control the quality of excitation and emission light.

4. An apparatus as set forth in claim 1 where the viewing window is suitable recessed within the housing and shaped so as to eliminate ambient light from the device.

Entire Device

Scale: ⌊ = 1cm

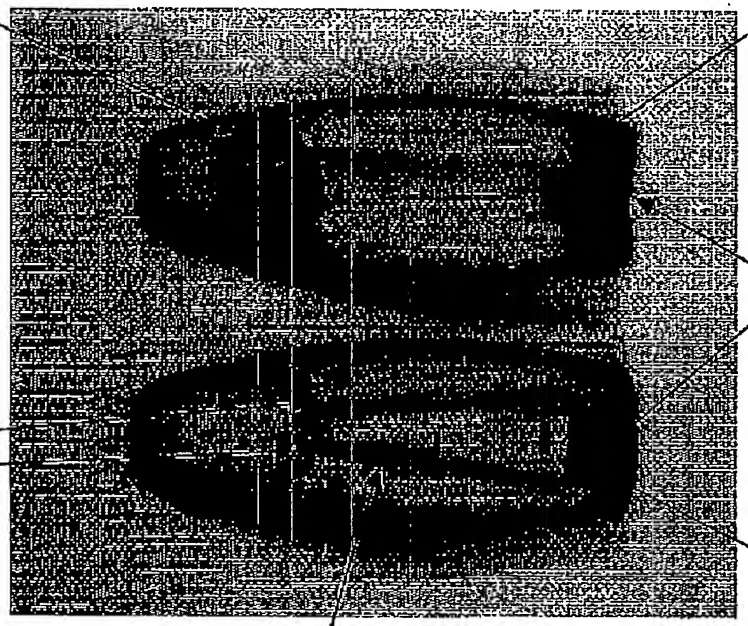
viewing window



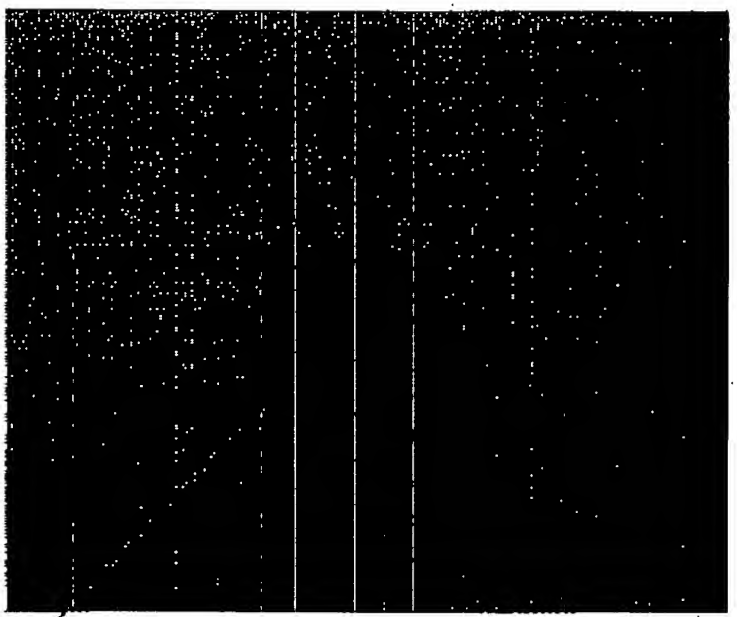
stick inserted here

housing

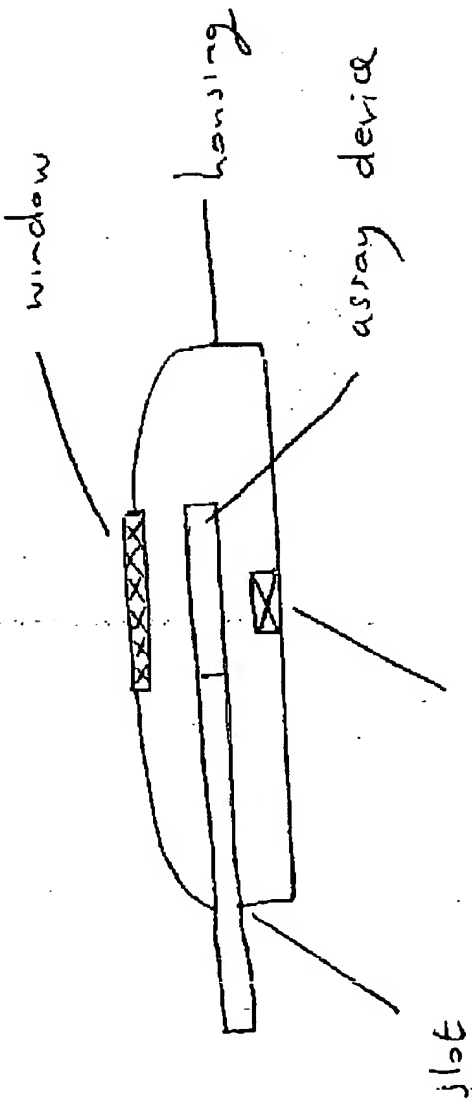
Horizontal Cross-Sections



Vertical View of Carrier Slot



carrier inserted into slot



4/4